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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,814	09/21/2007	**Eduardo Marban**	001107.00623	5612

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BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

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12/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,814	MARBAN ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-97* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-97 are presently pending, as originally-filed, and subject to the following restriction and elections of species:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 11-15, drawn to an assay system comprising a co-culture of cardiac myocytes and skeletal muscle myoblasts and a means for measuring electrical coupling of cells.

Group II, claim(s) 2-3 and 11-15, drawn to an assay system comprising a co-culture of cardiac myocytes and skeletal muscle myoblasts and a means for measuring electrical coupling comprising a voltage-sensitive dye.

Group III, claim(s) 4-5 and 11-15, drawn to an assay system comprising a co-culture of cardiac myocytes and skeletal muscle myoblasts and a means to measure electrical coupling comprising a calcium ion indicator.

Group IV, claim(s) 6 and 11-15, drawn to an assay system comprising a co-culture of cardiac myocytes and skeletal muscle myoblasts and a patch clamp apparatus.

Group V, claim(s) 7 and 11-15, drawn to an assay system comprising a co-culture of cardiac myocytes and skeletal muscle myoblasts and a means to measure conduction velocity.

Group VI, claim(s) 9 and 11-15, drawn to an assay system comprising a co-culture of cardiac myocytes and skeletal muscle myoblasts and a means to measure an action potential duration.

Group VII, claim(s) 10 and 11-15, drawn to an assay system comprising a co-culture of cardiac myocytes and skeletal muscle myoblasts and a means to to measure electrical coupling of cells and an electrode.

Group VIII, claim(s) 16 and 26-30, drawn to a method of measuring arrhythmias in cardiac cells *in vitro,* comprising: measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts.

Group IX, claim(s) 17-18 and 26-30, drawn to a method of measuring arrhythmias in cardiac cells *in vitro,* comprising: measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts through use of a voltage-sensitive dye.

Group X, claim(s) 19-20, 24, and 26-30, drawn to a method of measuring arrhythmias in cardiac cells *in vitro,* comprising: measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts through use of a calcium ion indicator.

Group XI, claim(s) 21 and 26-30, drawn to a method of measuring arrhythmias in cardiac cells *in vitro,* comprising: measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts through use of a patch clamp apparatus.

Group XII, claim(s) 22 and 26-30, drawn to Group VIX, claim(s) 17-18, drawn to a method of measuring arrhythmias in cardiac cells *in vitro,* comprising: measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts through measurement of conduction velocity.

Group XIII, claim(s) 23 and 26-30, drawn to a method of measuring arrhythmias in cardiac cells *in vitro,* comprising: measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts through measurement of action potential duration.

Group XIV, claim(s) 25 and 26-30, drawn to a method of measuring arrhythmias in cardiac cells *in vitro,* comprising: measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts through use of an electrode.

Group XV, claim(s) 31-33 and 39-42, drawn to a method of administering to myoblasts a lentivirus comprising a transgene encoding a connexin, wherein the connexin is expressed.

Group XVI, claim(s) 34 and 39-42, drawn to a method of administering to myoblasts a lentivirus comprising a transgene encoding a connexin, wherein the connexin is expressed, and the myoblasts are transplanted into a recipient mammal.

Group XVII, claim(s) 35 and 39-42, drawn to a method of administering to myoblasts a lentivirus comprising a transgene encoding a connexin, wherein the connexin is expressed, and the myoblasts are transplanted into a recipient mammal heart.

Group XVIII, claim(s) 36 and 39-42, drawn to a method of administering to myoblasts a lentivirus comprising a transgene encoding a connexin, wherein the connexin is expressed, and the myoblasts are transplanted into a recipient mammal brain.

Group XIX, claim(s) 37 and 39-42, drawn to a method of administering to myoblasts a lentivirus comprising a transgene encoding a connexin, wherein the connexin is expressed, and the myoblasts are transplanted into a recipient mammal muscle.

Group XX, claim(s) 38 and 39-42, drawn to a method of administering to myoblasts a lentivirus comprising a transgene encoding a connexin, wherein the connexin is expressed, and the myoblasts are transplanted into a recipient mammal uterus.

Group XXI, claim(s) 34 and 39-42, drawn to a method of administering to myoblasts a lentivirus comprising a transgene encoding a connexin, wherein the connexin is expressed, and the myoblasts are transplanted into a recipient animal.

Group XXII, claim(s) 43-56, drawn to a method of treating myoblasts, comprising transforming them to express connexin transgenically, and transplanting the myoblasts into an organ which is responsive to electrical stimulation.

Group XXIII, claim(s) 57-70, drawn to a method of treating myoblasts, comprising transforming them to express a calcium channel subunit transgenically, and transplanting them into an organ of a mammal which is responsive to electrical stimulation.

Group XXIV, claim(s) 71-84, drawn to a method of treating myoblasts comprising administering a nucleic acid encoding an siRNA for a potassium channel, with specific characteristics, and transplanting the cells into an organ of a host mammal.

Group XXV, claim(s) 85 and 87-88, drawn to a method of treating cells for use in cell transplantation, comprising administering to the cells a lentivirus encoding connexin, wherein the connexin is expressed.

Group XXVI, claim(s) 86 and 94-96, drawn to a method of treating cells for use in cell transplantation, comprising administering to the cells a lentivirus encoding connexin, wherein the connexin is expressed, wherein the cells are selected from a Markush group.

Group XXVII, claim(s) 89-93 and 97, drawn to a method of treating cells for use in cell transplantation, comprising administering to the cells a lentivirus encoding connexin, wherein the connexin is expressed, and transplanting the cells into a recipient host mammal.

The inventions listed as Groups I-XXVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-VII share a special technical feature of a sytem comprising a coculture of cardiac myocytes and skeletal muscle myoblasts, and a means for measuring electrical coupling. Reinecke, et al. (2000) The Journal of Cell Biology, 149(3): 731-40 teaches such, as is indicated by the title (not cited, as Applicant has aleady cited, and will be addressed at the first action on the merits). Groups VIII-XIV share a special technical feature of measuring an electrical property of a monolayer of cardiac myocytes and skeletal muscle myoblasts, and such is also shown in Reinecke. Groups XV-XXI share a special technical feature of transforming myoblasts to express a connexin. Suzuki, et al. (2001) Journal of Thoracic and Cardiovascular Surgery, 122(4): 759-66 (ABSTRACT ONLY) teaches transforming myoblasts to express connexin transgenically, and it would be obvious to do so

utilizing a lentiviral vector, as lentiviral vectors are already known to transform differentiating cells like myoblasts (official notice). The practitioner would do so to obtain the same transgenic expression, and expect success as the use of vectors is well known in the Art. Groups XXV-XXVII share a special technical feature of transforming a cell to express connexin with a lentiviral vector. Similar to above, Suzuki makes obvious the special technical feature. Groups I-VII, VIII-XIV, XV-XXI, XXII, XXIII, XXIV, and XXV-XXVII are distinct in sharing no common structure. Moreover, each invention requires distinct considerations for art and examination such that it demonstrates there is no general inventive concept shared between the inventions.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Commensurate with the invention chosen:

Applicant is required to choose a cardiac myocyte of Claims 11-15, 26-29, 39-41, 53-55, 67-69, and 81-83;

Applicant is required to choose a connexin of Claims 44-45 and 87-88;

Applicant is required to choose an organ of Claims 49-52, 63-66, 77-80, and 90-93;

Applicant is required to choose a subunit of Claims 58-59; and

Applicant is required to choose a cell type of Claims 86 and 94-96.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of

an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the various cell types, organs, and subunits are known in the art, and therefore, there is no special technical feature shared. Moreover, each has its own structure and therefore function, which requires distinct considerations for art and examination. Hence, there is not general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633